CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Food Labeling: Safe Handling Statements:
Labeling of Shell Eggs;
Shell Eggs: Refrigeration of Shell Eggs
Held for Retail Distribution;
Proposed Rule
Docket Nos. 98N-1230, 96P-0418, and 97P-0197
64 Fed.Reg. 36492 (July 6, 1999)

On behalf of the Center for Science in the Public Interest (CSPI) and fellow Safe Food Coalition member Consumer Federation of America, we appreciate this opportunity to comment on the Food and Drug Administration's (FDA's) proposed rule to require safe-handling statements on shell egg packaging and to require refrigeration of shell eggs at retail establishments. CSPI is a non-profit consumer advocacy organization focusing largely on nutrition and food-safety policies. We accept no industry or government funding and are supported almost entirely by the one million subscribers to our *Nutrition Action Healthletter*. CSPI has been advocating reform of the federal egg-safety system for many years and has petitioned FDA for changes to protect consumers from the hazards posed by shell eggs infected with the bacterium *Salmonella enteritidis* (SE).

We applaud FDA for taking important steps to improve shell-egg safety at the retail and consumer level. Ensuring that retail shell eggs are refrigerated at temperatures that prevent SE growth and alerting consumers about the potential risk posed by contaminated eggs should help to reduce the illnesses and deaths attributed to SE-contaminated eggs. However, more action is needed than is proposed in this current notice if the federal government and the industry are to seriously reduce or even eliminate SE-contaminated eggs as a health threat in this country. Below, after specifically commenting on the proposed refrigeration and labeling rules, we describe the crucial components of a successful egg-safety system that FDA has omitted from its proposal, including a mandatory on-farm quality assurance program that includes SE testing and diversion, a sell-by date on eggs at retail, a ban on eggs that have-surpassed the sell-by date, and other safeguards.

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1. FDA's Proposed Refrigeration Requirements

A. Refrigeration Requirements for Shell Eggs at Retail Must Prevent Growth

CSPI applauds FDA for proposing to require retail establishments to keep all shell eggs refrigerated. The lack of such a requirement has long been a gaping hole in the egg-safety net. However, the proposed refrigeration requirement is not sufficiently protective of public health for a number of reasons.

FDA has chosen 45°F as the required ambient temperature for refrigeration on the basis of studies that do not provide a sound scientific foundation for the requirement. In fact, none of the articles FDA cites in support of the proposed refrigeration requirement examined SE growth in eggs stored under conditions that simulate actual commercial storage conditions. Instead, each experiment cited by FDA involved only a small number of eggs that were refrigerated under artificial conditions. As a result, storage conditions in those studies were such that the ambient storage temperature was equivalent or nearly equivalent to the eggs' internal temperature, which is the variable that most influences SE multiplication.]

By contrast, commercially stored egg cartons can be placed on pallets in large numbers and stacked to high levels in high-volume coolers. Under such storage conditions, the eggs' internal temperature and the cooler's ambient temperature may differ by a substantial amount, especially for centrally located eggs that are insulated by surrounding eggs and therefore are exposed to warmer temperatures. Such effects have been detected in studies examining the temperature patterns in commercial egg transport vehicles and the rates at which stored eggs cool when packed in different configurations.' Of particular relevance is the finding in one such study that coolers produce a temperature gradient in which centrally located eggs are significantly warmer than those stored in relatively "exposed" positions on the edges of storage flats. Because of that gradient, eggs on the edges cool far more quickly than those stored in more central locations.[3]

Because such temperature gradients are produced in coolers that contain large numbers of eggs, the proposed 45 °F ambient temperature standard will not ensure that centrally located eggs are actually exposed to 45 °F in their micro-environment. Consequently, those eggs may not reach an internal temperature that is capable of preventing SE growth. To avoid this problem,

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[1] K. E. Anderson et al., "Legislation Ignores Technology," Egg *Industry,* Sept./Oct, 1992, p. 11.

[2] B. L. Darmon et al., "Temperature Patterns in Commercial Egg Transport Vehicles," *Journal of Applied Poultry Research*, Vol. 3 (1994), pp. 193-198; J.J.R. Feddes et al., "Internal Cooling Rates of Stored Eggs: Effects of Packing and *Egg* Size." *Journal of Applied Poultry Research,* Vol. 2 (1993), pp. 324-329 [hereinafter cited as *Internal Cooling Rates].*

[3] *Internal Cooling Rates*, pp. 326-328.

FDA should revise its proposed rule to require that eggs be stored at 41 °F, which will provide a margin of safety for eggs stored in large retail coolers.

The margin of safety provided by a 41 °F ambient temperature standard is also necessary to protect consumers from eggs that have been temperature abused at any point on the farm-to-retail continuum. Not surprisingly, studies show that SE grows more rapidly in temperature abused eggs." For instance, one study found that SE grew more rapidly in eggs exposed to temperature fluctuations between 64°F and 86°F than in eggs stored at 68°F. SE populations in the majority of eggs that experienced temperature fluctuations were higher than 10^6 cfu/egg after only 10 to 14 days.[5] While temperature fluctuations closer to 4.5 °F may result in less dramatic growth, such temperature fluctuations can be minimized by using an ambient refrigeration temperature of 4 1 °F or less.

Even absent temperature abuse, eggs may arrive at retail establishments at temperatures that promote SE growth. For example, in the preamble to its proposed rule FDA states that at the time eggs are packed, their internal temperature reaches 70 to 80°F while processors hold them at temperatures of 45 to 60°F.[6] During transportation, the internal temperatures of eggs are between 50 and 80°F.[7] Therefore, eggs often arrive at retail stores with internal temperatures well above 45 "F. Requiring a retail refrigeration temperature of 41 °F would minimize the time it would take for those eggs to reach a safe internal temperature.

In summary, the commercial realities of the egg industry are such that eggs are likely to have been exposed to temperatures that promote SE growth -- sometimes for long periods of time -- before they reach the retail establishment, and once at retail the eggs may be stored in coolers that do not assure a uniform ambient temperature for all eggs. Given those realities and the fact that maintaining eggs at low temperatures is crucial to preventing growth of SE to potentially dangerous levels, FDA should revise its proposed rule to require a retail refrigeration temperature of 41 "F. The tremendous health threat posed by SE-contaminated eggs warrants a significant margin of safety.

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[4] C. E. Clay and R. G. Board, "Growth of *Salmonella enteritidis* in Artificially Contaminated Hens' Shell Eggs," *Epidemiology and Infection,* Vol. 106 (1991), pp. 271-281.

[5] T.J. Humphrey and A. Whitehead, "Egg Age and Growth of *Salmonella enteritidis* PT4 in Egg Contents," *Epidemiology and Infection,* Vol. 111 (1993), p. 214.

[6] Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution: Proposed Rule," *Federal Register.* Vol. 64, No. 128 (1999), p. 36494, [hereinafter cited as *Labeling and Refrigeration of Shell Eggs, Proposed Rule].*

[7] *Ibid.*

B. The Refrigeration Requirement Should be Consistent with Requirements for Other Potentially Hazardous Foods

The proposed 45 °F requirement is inconsistent with the refrigeration requirement established by the 1999 FDA *Food* Code. That requirement mandates a storage temperature of 41 °F or less for "potentially hazardous" foods.' In the preamble to its proposed rule, FDA acknowledges that eggs are considered potentially hazardous under the *Food Code* and "encourages" retailers to store their eggs at a temperature below the proposed temperature of 45 °F.[9] As the agency points out, "[i]t may be most practical for establishments to have one requirement for a maximum refrigeration temperature for all potentially hazardous foods.[10]" We agree: FDA should require what it encourages and set the mandatory refrigeration temperature for shell eggs at retail at 41 "F.

C. Stringent Enforcement is Crucial to an Effective Rule

FDA has requested comments on how state, local, and federal regulators can best implement and enforce the proposed refrigeration requirement. To ensure strict enforcement of that requirement and any other regulations to reduce the risks posed by eggs, FDA should play a stronger role at the retail level. Because the majority of SE outbreaks are caused by problems in commercial venues, with the food source being undercooked eggs, it is especially important that FDA regulate the handling of shell eggs at retail." In a survey of 45 state and local agencies, CSPI found that many state and local governments have failed to adopt new recommendations in the *Food Code* in a timely manner. In fact, less than one-third of the jurisdictions we surveyed enforced the minimum cooking temperature for eggs."

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[8] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, *Food Code,* (Springfield, VA: U.S. Department of Commerce, 1999), § 3-501.14 [hereinafter cited as 1999 *Food Code].*

[9] *Labeling and Refrigeration of Shell Eggs, Proposed Rule.* p. 36500

[10] *Ibid.*

[11] US Department of Agriculture, Food Safety and Inspection Service, and Department of Health and Human Services, Food and Drug Administration, "*Salmonella* Enteritidis in Eggs; Advanced Notice of Proposed Rulemaking," *Federal Register,* Vol. 63, No. 96 (1998), p. 27504 [hereinafter cited as *Salmonella Enteritidis in Eggs*].

[12] Caroline Smith DeWaal and Elizabeth Dahl, *Dine at Your Own Risk: The Failure of Local Agencies to Adopt and Enforce national food Safety Standards for Restaurants,* (Washington, DC: Center for Science in the Public Interest, November 1996), p. 17.

FDA proposes to authorize those states "able and willing"[13] to enforce the proposed regulations. Before permitting state or local agencies to assume responsibility for implementing and enforcing the egg-safety requirements set forth in its proposed rule, FDA should evaluate each state or local program to ensure that it is has the expertise and resources necessary to do the job well. If the state and local agencies do not have those capabilities, FDA should be prepared either to aid the agencies with training and/or resources or to enforce the rules itself. Moreover, FDA should perform comprehensive annual reviews to determine whether state and local regulators are consistently enforcing the federal standards. Only those state and local agencies that satisfy strict federal performance standards should be permitted to enforce the proposed regulations.

Whether enforcement is done by federal, state, or local authorities, inspectors should conduct temperature checks of the eggs' environment with accurate thermometers at least two times a year. Since that is the inspection frequency recommended for retail establishments in the Food *Code*,[14] inspections could be conducted during regular retail inspections. In addition, to ensure that storage temperatures are maintained at or below the mandated temperature at all times, temperature recording devices that continuously monitor and record the temperature inside storage areas should be required, and records should be made available to inspectors.

CSPI agrees that eggs in violation of the temperature requirements should be diverted or destroyed. However, we oppose the 1 O-working-day allowance for the destruction of the eggs. FDA provides no rationale for that length of time,[15] and 10 working days seems to be an unnecessarily long period of time that could allow for inadvertent repacking of the eggs or opportunities for other errors. No more than three to five working days should be allowed for diversion or destruction of noncompliant eggs to minimize the likelihood of errors.

II. FDA's Proposed Labeling Requirements:

A. FDA Should Require a Cautionary Statement, Rather Than Safe-Handling Instructions

CSPI is pleased that FDA intends to require that all egg cartons bear a label alerting consumers to the threat of hazardous bacteria in shell eggs, as we requested in our May 14, 1997

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[13] *Luheling and Refrigeration of Shell Eggs, Proposed Rule.* p. 36502.

[14] *1999 Food Code*, § *S-401.10.*

[15] *Labeling and Refrigeration of Shell Eggs, Proposed Rule,* p. *36500.*

citizen petition.[16] Participants in FDA's focus groups confirmed that consumers would like handling instructions on egg cartons.[17]

We emphasize, however, that such labeling should be considered no more than an interim measure intended to protect consumers until the federal government and the egg industry are able to control the problem of SE in shell eggs. As explained more fully below, measures designed to eliminate the pathogen before it ever enters eggs, including mandatory on-farm quality assurance programs, are necessary to achieve the eventual elimination of illnesses and deaths from SE-contaminated eggs. Our ultimate goal is that such programs eventually will make cautionary labeling unnecessary.

There is much to commend in FDA's proposed labeling requirement. CSPI strongly supports the agency's tentative conclusion that it is essential that the label statement alert consumers about the exact nature of the hazard posed by shell eggs, specifically that eggs may contain pathogens known to cause serious, life-threatening illness. FDA should reject arguments to omit such a description from the advisory.

CSPI also supports FDA's tentative conclusion that the label statement should describe ways consumers can reduce their risks of infection. Providing such information is an important part of the farm-to-table food-safety approach necessary to reduce illness from SE. CSPI also agrees that the labeling requirements should apply to eggs shipped intra-state as well as inter-state. Omitting that requirement would create a gap that could allow the spread of SE.

However, we have several concerns about the specific requirement proposed by FDA. First, as we explained in our citizen petition, the serious public-health threat posed by SE in eggs warrants a cautionary label on all egg cartons that plainly states to consumers that the way they are accustomed to eating eggs may no longer be safe. The proposed label statement, which is styled as "safe handling instructions," does not achieve that objective. CSPI continues to believe that its proposed label, which uses the term "Caution" as a signal word, is the best way to communicate the message that eggs may be unsafe quickly and unambiguously.

Because SE presents a considerable public-health threat, we urge FDA to redraft its proposed labeling regulation to require a "caution" statement rather than a set of safe-handling instructions. FDA did not consider the word "caution" in its discussion of signal statements in the preamble to the proposed rule. The label proposed by CSPI, unlike one that uses the signals "warning" or "danger," is unlikely to cause consumers to avoid a product altogether.

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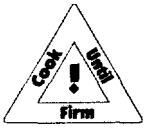
[16] Center for Science in the Public Interest, "Petition for Regulatory Action to Require That (I) Warning Labels About the Risks of *Salmonella enteritidis* (SE) Be Placed on Shell Egg Cartons and (2) SE Control HACCP Programs Be Implemented on All Egg-Producing Farms," Food and Drug Administration Docket No. 97P-0197, May 14, 1997.

[17] *Labeling und Refrigeration of Shell Eggs, Proposed Rule,* p. *36503.*

CSPI agrees with FDA's decision to add I refrigeration advisory to the label. However, for the sake of brevity, the statement should be shortened to "Keep refrigerated," instead of "Keep eggs refrigerated" or "Keep eggs refrigerated until cooked," as suggested in FDA's notice.'* We have modified our proposed label to incorporate the refrigeration notice as follows:



Caution: Eggs may contain illnesscausing bacteria. Keep refrigerated. Do not eat raw. Cook until yolk is firm.

B. The Proposed Label Statement is Too Long

FDA should pare down its proposed label statement. The proposed language is far too long and detailed. Studies on the effectiveness of labels show that too much information causes consumers to filter out key elements of the message."

So that it may be quickly read and understood by consumers, the statement should be bolder and briefer, and should use fewer words and bigger print. To accommodate all of the proposed language, the statement would have to appear in small, hard-to-read print. That is a significant concern, especially because elderly people, many of whom have impaired vision, are among those at greatest risk from SE-contaminated eggs.

FDA should not include special instructions in the proposed label statement advising at-risk consumers or their caretakers to avoid shell eggs. While this information is important, it would add too much additional language to the label. Other education approaches should be developed to target especially vulnerable consumers and their caretakers.

FDA also should eliminate the words "cook foods containing eggs thoroughly before eating."[20] Cooking egg-containing foods to a safe temperature may be impossible some dishes, such as meringue and Caesar salad dressing, since undercooked or raw eggs are an inherent part of those dishes. The only safe solution in those instances would be to use pasteurized eggs or avoid the dish entirely. Since the proposed language could not be followed in all cases, it should not be included in the label.

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[18] *Ibid.*. p. 36503- *36504.*

[19] Mark Lehto and James Miller, *Warnings: Fundamentals, Design, and Evaluation Methodologies, Vol.* I, (Ann Arbor. MI: Fuller Technical Publications, 1987), **pp.** 61-68.

[20] *Labeling and Refrigeration of Shell Eggs, Proposed Rule,* **p. 36504.**

Nor should FDA require that the phrase "use pasteurized eggs for recipes requiring raw or partially cooked eggs"[21] appear on the label. Consumers cannot readily purchase certain pasteurized egg products, such as egg whites, in retail stores. In fact, CSPI has tried to obtain such products, but we have only been able to obtain examples destined for institutional or restaurant use.

C. Modifications Should be Made to the Location and Size Requirements for the Label

We applaud FDA's decision to include in its proposed rule specific requirements relating to the label statement's type size and font. We also support the requirement that the statement be prominent and conspicuous and appear in a hairline box. However, we urge the agency to amend its proposed rule to make the statement even more visible to consumers, including those with impaired vision.

Specifically, FDA should require that the label be prominently placed on the lid of the egg carton. Although the agency's focus groups felt the label could also be placed on the nutrition panel, more research needs to be conducted to see if consumers will in fact notice a label placed there.

In addition, the label should be enclosed by a hairline box with adequate space around the statement and the words should be printed in a dark color on a light background to enhance its legibility." The statement should use a font size no smaller than 12-point, which would ensure that the statement is large enough to be legible to most consumers and would reduce the likelihood that the statement would be obscured by other label elements."

For eggs that are repacked or used in institutions, the cautionary statement should be on the package of eggs and not on the invoice or product specification sheet. because those documents may become separated from the eggs and not read by food handlers. The label should also be required on any package containing shell eggs or parts of shell eggs.

The label should include a graphic symbol to improve consumer retention of the message. To maximize the label's effectiveness, it should include an exclamation point inside a triangle, as found on CSPI's proposed label. Such a symbol would serve as a reminder that eggs may contain harmful bacteria and that consumers must take precautions when preparing eggs to

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[21] *Ibid.*

[22] See, *e.g.*, 21 C.F.R. § 867(e) (specifications for olestra warning label).

[23] The minimum type size should be 12 point based upon the recommendations of experts who have conducted readability research on older persons. AARP. *Comments in re: Food and Drug Administration. Food Labeling: Safe Handling Stutements: Luheling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution*, Docket Nos. 98N-1230, 96P-0418, 97P-0197, Sept. 20, 1999. p. 4.

protect themselves. Ideally, the symbol should be understandable to consumers who understand little or no English.

Since other foods can also be hazardous to consumers, the graphic symbol could become a universal signal to alert susceptible populations to the risks of foodborne pathogens in those foods. An education campaign could be developed to teach the public, particularly susceptible populations and their care givers, about the symbols and about foodborne illnesses.

The meat and poultry safe-handling label, with its graphic symbols that convey and support the written message, make it easier for consumers to understand the instructions. A symbol on egg cartons would similarly convey and reinforce the important written information to consumers.

D. FDA Should Consider a Two-Tiered Labeling Scheme for Eggs Produced Under On-Farm Egg Quality Assurance Programs

At the recent public meeting on egg safety held by the President's Food Safety Council, a representative from the Pennsylvania Department of Agriculture stated that he opposes a carton label that refers to illness-causing bacteria or functions as a warning in any way. In his view, requiring such a statement would unfairly penalize eggs that have been produced under the Pennsylvania Egg Quality Assurance Program (PEQAP), a successful on-farm quality assurance program described in detail below.

While CSPI does not agree that the carton label should omit the reference to the potential hazard posed by shell eggs, a somewhat less stringent warning may be appropriate for eggs produced under PEQAP or an equivalent on-farm quality assurance program that includes both microbial testing for SE and diversion of contaminated eggs.

Under a two-tiered labeling scheme, cartons of eggs produced under such programs could bear a label such as the following: "SAFE HANDLING INSTRUCTIONS: To prevent illness, keep refrigerated. Do not eat eggs raw. Cook until yolk is firm." By contrast, cartons of eggs not subject to such a quality-assurance program would contain the cautionary label proposed by CSPI, including the reference to "illness-causing bacteria."

Once again, CSPI emphasizes that the proposed two-tiered labeling system, like the overall carton-label requirement, should be viewed merely as a temporary solution pending the universal implementation of on-farm SE-control programs. Until then, however, the two types of labels would enable consumers to distinguish between eggs that have been produced under the auspices of such programs and those that have not.

E. In-Shell Pasteurized Eggs Should be Exempt from the Labeling Requirement

Eggs treated with an in-shell pasteurization process should be exempt from the labeling requirement proposed by FDA, provided the pasteurization process satisfies certain stringent criteria. Specifically, the process should be part of a hazard analysis and critical control point (HACCP) program, including validation of the pasteurization process and continual verification that it is achieving the requisite degree of pathogen reduction. FDA should also require packing, transportation, and retail establishments handling these specially treated eggs to implement post-pasteurization controls to prevent recontamination. In addition, a label informing handlers and consumers not to mix the pasteurized eggs with unpasteurized eggs should be required. That label should also have the same placement, size, and other requirements as the label required for unpasteurized eggs.

III. FDA Should Take Additional Steps to Improve Egg Safety, Including Mandating On-Farm Quality Assurance Programs

As previously stated, though FDA's proposed refrigeration and labeling rules will help protect consumers from the dangers posed by SE-contaminated eggs, much more must be done to achieve the federal government's goal of eventually eliminating the deaths and illnesses caused by SE in eggs.[24] Below, CSPI describes several important changes to the existing egg-safety system that are necessary to achieve that objective.

A. FDA Should Mandate On-Farm Quality Assurance Programs that Include SE Testing and Diversion

Refrigeration and labeling requirements may help protect consumers by reducing SE growth in shell eggs and encouraging proper cooking and safe handling, but such measures obviously cannot stop the pathogen from entering eggs in the first place. In the absence of widely available means to kill the bacteria or fully eliminate it from flocks, comprehensive on-farm quality assurance programs, including preventive controls, microbial testing, and diversion of contaminated eggs, are needed. FDA should mandate such programs as the cornerstone of a new national regulatory program for shell eggs.

By requiring microbial testing for SE and diversion of contaminated eggs to pasteurization plants, FDA would provide egg producers with a strong incentive to develop and implement effective controls to minimize the risk of contamination on the farm Real advances

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[24] As CSPI stated in its comments on the egg-safety strategy developed by the President's Food Safety Council, the federal government should have as its objective the full elimination of egg-related SE illnesses by 2005. Center for Science in the Public Interest, *Comments in re: Food und Drug Administration. Egg Safety Action Plan, Public Meeting,* Docket No. 98N- 1230, September 11, 1999, p. 2.

in egg safety should occur as the threat of lost revenue from egg diversion encourages producers to use the best preventive technologies to eliminate SE from their flocks.

At the same time, diversion of contaminated eggs would help ensure that such eggs never reach the market, where they can sicken consumers. In a risk assessment of the shell egg production system, researchers estimated that diverting just 25 percent of eggs from SE-positive flocks would reduce human illness by 25 percent.[25] Diverting all eggs from SE-positive flocks should have an even greater positive impact on human health.

The effectiveness of on-farm quality assurance programs is not just theoretical. The success of two such programs, the Pennsylvania Egg Quality Assurance Program and Sweden's on-farm SE-control program, demonstrates that the strategy outlined by CSPI actually works.

The Pennsylvania Egg Quality Assurance Program began as a federal initiative. To address the high incidence of SE in Pennsylvania egg-producing flocks, the Animal and Plant Health Inspection Service (APHIS) sponsored the *Salmonella* Enteritidis Pilot Program.[26] That voluntary program, which utilizes a HACCP model, has demonstrated that farm control measures can successfully reduce SE in eggs. When the program was implemented in 1992, multiple manure and other samples were taken from the houses of 70 laying flocks. In 1992, 38 percent of laying houses had at least one SE positive sample, but by 1995, only 13 percent of flocks had a positive SE sample. In 1992, 23 percent of all the samples tested positive for SE, which dropped to only 3.2 percent of samples in 1995.[27] Human illness from SE in the market area for Pennsylvania eggs (New York, New Jersey, and Pennsylvania) also decreased between 1992 and 1995.[28] A team of 15 scientists from Federal and State government agencies attributed at least part of this decrease to the Pennsylvania program and recently recommended that the interventions in the Pennsylvania program be implemented by all egg producers."

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[25] *Salmonella* Enteritidis Risk Assessment Team, for the U.S. Department of Agriculture, Food Safety and Inspection Service, "*Salmonella* Enteritidis Risk Assessment. Shell Eggs and Egg Products. Final Report," June 12, 1998, p. 2.5 [hereinafter cited as *Salmonella Enteritidis Risk Assessment].*

[26] *Salmonella Enteritidis in Eggs,* pp. 27X0-27506.

[27] "A New Layer of Food Safety Assurance?," *Food Safety Digest,* March/April 1996, p. 5; telephone conversation with David Henzler, Pennsylvania Department of Agriculture, Harrisburg, PA, April 18, 1997.

[28] Allan Hogue, et al., *Salmonella Enteritidis Review Team Report, Final,* January 18, 1997, pp. 3, 9-10.

[29] *Ibid.,* pp. I-3, 9-10.

Despite its success, the program's funding was cut by Congress in 1995.[30] However, the program continues on a voluntary basis as the Pennsylvania Egg Quality Assurance Program (PEQAP).

Following are requirements from the PEQAP program that should be incorporated into an FDA-mandated on-farm quality assurance program for shell-egg producers:

a. Chicks for layer flocks must be obtained from breeder flocks monitored for SE. Manure samples from the chicks must be tested at the time the chicks are delivered, and then again when the chicks are 10 to 15 weeks old.

b. Manure samples from layer flocks must be regularly tested for SE when the hens are 29 to 3 I weeks of age and again at 44 to 46 weeks of age. If the samples are positive, the houses must be thoroughly cleaned and disinfected between flocks.

c. When manure samples are positive, eggs must also be tested. A total of 480 eggs must be tested, cultured in pools of 20 eggs each, every two weeks for eight weeks. Even if the eggs test negative, monthly egg sampling is required for the life of the flock.

d. Where testing of eggs shows that some are positive for SE, all eggs from that flock must be diverted to pasteurization plants. Before the eggs from that flock can be sold as shell eggs again, a total of 4,000 eggs over eight weeks must test negative for SE.

e. Biosecurity programs and rodent control measures for layer houses must be implemented.

f. Eggs must be kept refrigerated at all times."

In addition. producers should keep records to establish compliance with their program. FDA or FDA-certified state inspectors should verify producer compliance by reviewing those records. The testing of samples should be monitored by FDA. Testing data should be submitted to the agency so the program can be evaluated and strengthened. Eggs that test positive for SE should be diverted from the fresh-shell-egg market to egg pasteurization plants.

Sweden's SE-control program also shows what is possible when government and producers are committed to eliminating the human health-risk from this pathogen. The Swedish government has a rigorous control program directed at all types of *Salmonella* in both laying hens and broilers. The program requires testing of laying flocks at least three times during their lives,

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[30] Conversation with Robert Tauxe, Centers for Disease Control and Prevention, Washington, DC, Oct. 30, 1996: "FSIS Budget Set by House, Senate 'Not Encouraging,' Official Says," *Food Chemical News*, October 2, 1995. p. 43.

[31] Pennsylvania Poultry Federation, "Pennsylvania Egg Quality Assurance Program," May 1994.

with destruction of all flocks that are found to be SE-positive.'* The results have been impressive: between 1987 and 199.5, only five SE-infected flocks were identified in the entire country.[33]

The demonstrated success of both PEQAP and Sweden's SE-control program belies FDA's assertion that a "HACCP-like program is currently not feasible."[34] FDA should carefully examine those programs and use them as models in developing a national, mandatory on-farm egg quality assurance program.

Until such a program is developed, FDA should encourage producers to voluntarily adopt on-farm SE-control plans. FDA could encourage voluntary adoption by allowing producers with SE-control programs monitored by FDA to place a symbol or logo on their egg cartons indicating that the eggs were produced under such a program.[35] In addition, CSPI's proposed two-tiered labeling scheme would provide an incentive to implement on-farm quality assurance programs by permitting cartons of eggs from such programs to bear safe-handling instructions instead of the proposed cautionary label.

B. FDA Should Mandate a Retail Sell-By Date

FDA should set a sell-by date for fresh eggs of 30 days after the date of lay. That date should be prominently and conspicuously stamped on egg cartons using the first three letters of the month, the calendar date, and the year, so that consumers can readily determine when a package of eggs has exceeded the sell-by date.

A sell-by date of 30 days after lay is appropriate both because it is reasonable for consumers to expect that eggs sold as "fresh" are less than 30 days old and because of the safety risk posed by older eggs. Research shows that egg membrane degradation occurs as eggs age, increasing the risk that SE-infected eggs will contain high numbers of the bacteria.[36] The potential for membrane degradation is further increased when eggs are left in consumers' refrigerators for several weeks before they are eaten.

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[32] M. Wierup, et al., "Control of *Salmonella enteritidis* in Sweden," *International Journal of Food Microbiology,* Vol. 25 (1995), p. 224.

[33] *Ibid.,* p. *223.*

[34] *Labeling and Refrigeration of Shell Eggs, Proposed Rule,* p. 36.507.

[35] However, the symbol or logo should not state that the eggs are safe to eat raw or undercooked.

[36] T. J. Humphrey et al., "Numbers of *Salmonella* Enteritidis in the Contents of Naturally Contaminated Hens' Eggs," *Epidemiology and Infection,* Vol. 106 (199 1), p. 489; T. J. Humphrey and A. Whitehead, "Egg Age and the Growth of *Salmonella* Enteritidis PT4 in Egg Contents," *Epidemiology and Infection,* Vol. 1 1 1 (1993), p. 214.

A mandatory sell-by date will enable consumers to protect themselves from the risks of SE-contaminated eggs by helping them to purchase only eggs that have been stored for relatively short periods of time, and by encouraging them to cook those eggs quickly rather than storing them in their home refrigerators for extended periods. Currently, egg packages give consumers only limited guidance about the age of the eggs inside. While some producers voluntarily label their eggs with expiration dates, the only federal date-labeling requirement for eggs applies to those egg producers who participate in USDA's voluntary grading program, who must stamp the date of packaging on their egg cartons. Unfortunately, because of lax repackaging requirements (see below), the packaging date may bear very little relation to the actual age of the eggs. By mandating that the sell-by date appear in a readily understood form on the egg carton, FDA can help consumers avoid old, and potentially harmful, eggs.

In addition, FDA should establish a maximum expiration date for all shell eggs. Currently, many egg processors determine their, own expiration date." The maximum expiration date should be based on the growth of SE in eggs held at 41 °F, provided that FDA and USDA require this temperature for shell eggs from the time they leave the processing plant through the retail level. If they allow a higher temperature for eggs, such as 45 °F, the maximum expiration date should be based on the growth of SE in eggs at that temperature. A margin of safety accounting for potential time and temperature abuses should be factored into the expiration date. If eggs have exceeded the expiration date. they should be destroyed or sent to breaking plants to be pasteurized.

C. The Repackaging of Eggs Should Not Be Permitted

The repackaging and redating of old eggs misleads consumers, who have no way of knowing if a particular egg has been repackaged. Those practices. which have received national media attention," also pose a potential public-health risk by allowing SE more time to grow in the repackaged eggs, FDA should prohibit the industry from sending eggs that have been sitting at the retail level back to the processors to be rewashed and repackaged with fresh eggs. The agency should also prohibit -- or, at the very least, strictly limit based upon a scientific assessment of risk -- eggs that have been stored at packaging plants from being rewashed and repackaged with eggs that are fresh.

The Agricultural Marketing Service of the U.S. Department of Agriculture (USDA/AMS) recently proposed a rule that would withhold the USDA grademark from shell eggs that: (1) were laid more than 15 days prior to the date of packaging (effectively prohibiting repackaging of eggs older than 15 days); or (2) were previously shipped for retail sale (effectively prohibiting the

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[37] *Salmonella Enteritidis in Eggs. p.* 27507

[38] Dateline NBC. "Shell Game." air-date April 7. 1998, update April 21, 1999.

repackaging of eggs returned from retailers)." CSPI welcomes those changes in USDA/AMS's regulations, but notes that they apply only to the one-third of eggs in this country that are produced under the USDA voluntary grading program.[40] FDA should promulgate similar regulations for the remainder of the eggs produced in this country, so that consumers can be sure that old eggs will not be repackaged and sold as fresh eggs. As USDA/AMS concluded in developing its proposed rule, prohibiting the repackaging of eggs that are over 15 days old or have already been shipped to retail is commercially feasible and serves consumers' interests."

The public-health rationale for prohibiting or strictly limiting egg repackaging is clear. Both time and temperature are likely to be compromised in eggs that are repackaged, which are subject to greater temperature variations and are more likely to encounter temperature abuse while they are being stored and shipped back and forth between processors and retailers. Repackaged eggs are also washed a second time, which raises the temperature of eggs after they have aged significantly. The greater an egg's temperature, the faster bacteria that may be present will grow to high levels.[42] Based on those factors, repackaging increases the chance that an egg will become heavily contaminated with SE. Such an egg poses a much greater risk to consumers, since SE in heavily contaminated eggs can survive even standard cooking methods.[43]

If FDA can identify instances where repackaging can be done safely, the agency should mandate that repackaged eggs be packaged separately from fresh eggs. Repackaged eggs should be clearly labeled to indicate the original date of lay, and the package should state that the eggs should be thoroughly cooked before serving. Because cooking may not entirely eliminate SE from a highly contaminated egg,[44] the label should also state that repackaged eggs should not be eaten by young children, the elderly, or consumers with compromised immune systems.

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[39] U.S. Department of Agriculture, Agricultural Marketing Service, "Eligibility Requirements for USDA Graded Shell Eggs; Proposed Rule," *Federal Register*, Vol. 64, No. 143 (1999). pp. 40533-40525 [hereinafter cited as *USDA/A MS Repackaging Proposed Rule].*

[40] *Salmonella Enteritidis in Eggs,* p. *27507*

[41] *USDA/AMS Repackaging Proposed Rule,* p. 40523.

[42] C. J. Kim et al.. "Effect of Time and Temperature on Growth of *Salmonella* Enteritidis in Experimentally Inoculated Eggs," *Avian Diseases,* Vol. 33 (1989), pp. 735-742.

[43] A. M. Saeed and C. W. Koons, "Growth and Heat Resistance of *Salmonella* Enteritidis in Refrigerated and Abused Eggs," *Journal of Food Protection,* Vol. 56, No. 11 (1993), p. 930.

[44] *Ibid.*

D. Eggs Should be Cooled Before Being Packaged

As previously documented, today eggs often arrive at retail at temperatures well above 45 "F. FDA's proposed retail temperature requirement, together with USDA's new rule requiring eggs be stored at 45 °F ambient temperature after packaging,[45] may not succeed in reducing temperatures of all eggs to safe levels before they reach retail. Because of the insulating effects of commercial packaging systems, as well as the potential for temperature abuse at many points along the farm-to-table continuum, it is imperative that the temperature of eggs be quickly reduced immediately after lay. In the SE risk assessment, researchers calculated that there would be a 12 percent reduction in human illnesses from SE if eggs were immediately cooled after lay to an internal temperature of 45 °F and maintained at this temperature throughout the egg processing, distribution, and storage process. In comparison, the researchers calculated an eight percent reduction in human illnesses if eggs were cooled to an ambient temperature of 45 °F throughout the same process.[46]

Eggs should be required to be cooled ***before*** they are packed in pallets or cartons so that individual eggs will not be insulated from cooling temperature. FDA should develop regulations that will require the industry to follow the best available practices, including the use of rapid cooling technology and devices that maximize the exposure of all eggs to the cooling temperature.

IV. Conclusion

The refrigeration and labeling rules proposed by FDA should result in modest improvements in the existing federal egg-safety system. However, the proposed rules should be strengthened by reducing the maximum allowed retail refrigeration temperature from 45 °F to 41 °F, and by amending the required label statement as described above. The improvements suggested by CSPI would help ensure that the proposed rules do in fact reduce the illnesses and deaths caused by SE-contaminated eggs.

CSPI emphasizes, however, that our national egg-safety regulatory system has little prospect for success in eliminating SE-contaminated eggs as a public-health problem unless it requires on-farm quality assurance programs that include preventive controls, testing for SE, and diversion of contaminated eggs. Though temperature controls and labeling help prevent illnesses from contaminated eggs, on-farm monitoring and control programs would help stop eggs from

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[45] Department of Agriculture, Food Safety and Inspection Service, "Refrigeration and Labeling Requirements for Shell *Eggs," Federal Register,* Vol. 63, No. 166 (1998), pp. 4.5663-45675.

[46] *Salmonella Enteritidis Risk Assessment,* p. 2. The 12 percent and 8 percent reductions in illness attributed to better temperature control is minimal and further highlights the need for regulation on the farm to control for SE in shell eggs.

becoming infected with SE in the first place. As the successful Pennsylvania Egg Quality Assurance Program has shown, a well designed and closely monitored on-farm program can reduce SE contamination in egg-laying flocks and protect consumers of shell eggs.

CSPI has urged the President's Food Safety Council to set as its overarching goal the elimination of SE illnesses from eggs and egg products by 2005. To achieve that reasonable objective, FDA and the Council should act swiftly to develop and implement a national egg-safety plan that includes all of the critical elements described above, especially mandatory on-farm monitoring and control programs. The federal government and the egg industry currently have the tools necessary to stop SE-contaminated eggs from reaching consumers; consumers should not have to wait any longer for those tools to be put to effective use.

Sincerely,

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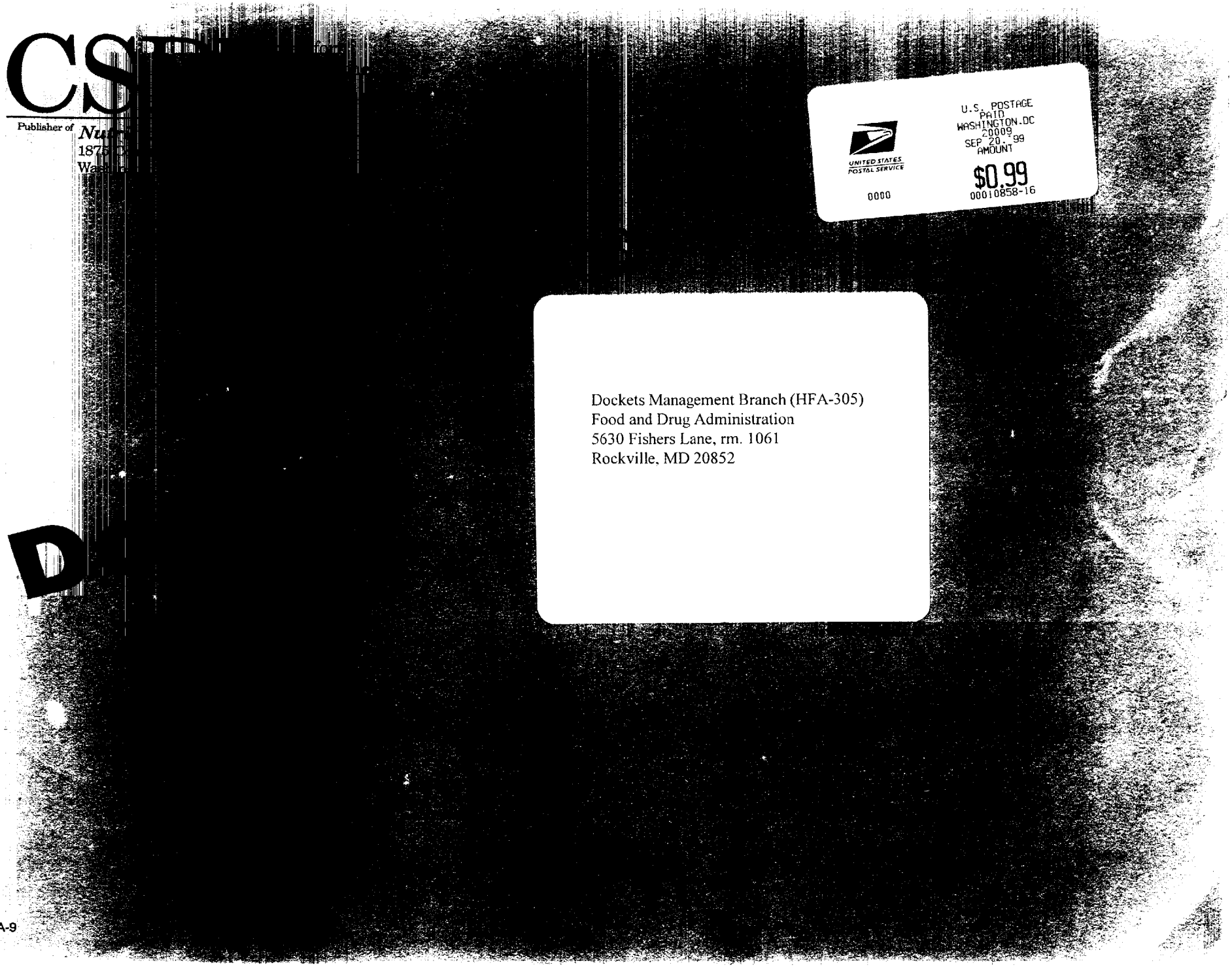
On behalf of:

Consumer Federation of America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